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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,862	12/17/2004	Isabelle Rault	OT/3-32536A	9982
1095	7590	07/13/2007	EXAMINER	
NOVARTIS			ALSTRUM ACEVEDO, JAMES HENRY	
CORPORATE INTELLECTUAL PROPERTY			ART UNIT	PAPER NUMBER
ONE HEALTH PLAZA 104/3			1616	
EAST HANOVER, NJ 07936-1080				
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			07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/518,862	RAULT ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	James H. Alstrum-Acevedo	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 April 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 18-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 18-47 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

**Claims 18-47 are pending.** Claims 35-47 are new. Applicants' cancelled claims 1-17 in a preliminary amendment. Receipt and consideration of Applicants' amended claim set and remarks/arguments are acknowledged.

### *Specification*

The objection to the specification for the improper use of the trademark HYDRASCAN® (pg. 5, 5<sup>th</sup> paragraph) **is maintained** for the reasons of record set forth on page 2 of the office action mailed on October 6, 2006.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** per Applicants' showing that the term "essential plant oil" is a term of art with an extremely broad definition.

### *Response to Arguments*

Applicant's arguments, see page 6, filed April 6, 2007, with respect to the rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite have been fully considered

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and are persuasive. The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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The rejection of claims 18-24 and 26-34 under 35 U.S.C. 103(a) as being unpatentable over Greve et al. (U.S. Patent No. 5,801,199) in view of Jacob et al. (US 2003/0060486) is maintained for the reasons of record set forth on pages 4-7 of the office action mailed on October 6, 2006. New claims 35-47 are appended to this rejection for the reasons of record. In summary, **claims 16=8-24 and 26-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greve et al. (U.S. Patent No. 5,801,199) in view of Jacob et al. (US 2003/0060486).**

#### *Response to Arguments*

Applicants' arguments filed April 6, 2007 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection by initially attacking the references individually and asserting that (1) the Greve reference teaches that compositions devoid of panthenol compounds are "severely limited"; (2) Jacob is allegedly deficient because it fails to expressly teach each and every member of Applicants' claimed Markush group; (3) Jacob is allegedly deficient for not expressly teaching the combination of a mucoadhesive polymer (i.e. hyaluronic acid or dermatan) with propylene glycol; (4) the Examiner is allegedly "picking and choosing" between different excipients taught by Jacob, which Applicants allege is inappropriate; (5) Jacob allegedly teaches away from the use of hyaluronic acid or dermatan as the mucoadhesive polymer because Jacob expresses a preference for homopolymers and copolymers based on acrylic acid and methacrylic acid; (6) Jacob's reference to propylene glycol as a humectant is allegedly irrelevant to nasal compositions; (7) the compositions taught by Greve and Jacob allegedly require a preservative because the exemplified compositions comprise

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a preservative; and (8) the combination of Greve and Jacob allegedly teaches away from compositions lacking a panthenol compound.

The Examiner respectfully disagrees with Applicants' arguments. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants' arguments (1) and (8) are unpersuasive because Applicants' utilize claim language that does not prohibit the presence of panthenol compounds. Furthermore, the teachings of Greve do not teach away from compositions lacking a panthenol compound, merely that compositions having a panthenol compound in admixture with xylometazoline or oxymetazoline hydrochloride have desirable properties, which enhance the utility of compositions comprising xylometazoline or oxymetazoline hydrochloride. Applicants' argument (2) is unpersuasive because a reference teaching at least one single component of a Markush group is sufficient to obviate a claimed compound or composition. Argument (3) is unpersuasive because Greve expressly teaches two of Applicants' claimed mucoadhesive polymers as suitable for use in Greve's combinations, and thus, it would have been obvious to use hyaluronic acid or dermatan sulfate as a mucoadhesive polymer. Argument (5) is unpersuasive because a reference's expressed preferences are not a teaching away, but merely the expression of an author's or inventor's preference. Arguments (4) and (6) are unpersuasive, because Greve expressly teaches that it is desirable to formulate the viscous mucoadhesive solution using only excipients that all major pharmaceutical regulating authorities consider safe, such as humectants. Thus, it would be obvious to include humectants in Greve's formulations.

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Furthermore, oral and nasal formulations are within the same field of endeavor, especially, because both the oral and nasal cavities comprise mucosal tissue and Greve's formulations are designed for mucosal administration. Argument (7) is unpersuasive, because Greve teaches that preservatives are optional ingredients; Jacob merely teaches a preference for compositions comprising preservatives; a reference is not limited to its exemplified embodiments nor are a references' preferences a teaching away. In paragraph [0030] of Applicants' specification, Applicants' assert that it is surprising that a consumer study found that Applicants' compositions were perceived as being more moisturizing. This is not unpersuasive, because humectants are characterized by moisturizing properties and propylene glycol is a well-known humectant as set forth on the record.

Regarding new claims requiring that the mucoadhesive polymer be chondroitin, chondroitin sulfate, or sodium hyaluronate, these polymers are obvious per the teachings of the combined prior art. It is noted that dermatan sulfate is also known as chondroitin B sulfate, and thus its synonym readily suggests chondroitin sulfate. Furthermore, a compound with at least one sulfate group would readily be recognized by an ordinary skilled artisan as being anionic (i.e. having a negatively charged substituent). Greve expressly teaches that polyanionic carbohydrate polymers and oligomers are known to have a beneficial effect in the treatment of mucosal disorders and that the nose comprises mucosal tissue. Chondroitin sulfate is a polyanionic carbohydrate polymer, thus it would have been obvious to an ordinary skilled artisan that chondroitin sulfate is a desirable component in mucosal compositions (e.g. nasal compositions). It is also noted that hyaluronic acid is also known as hyaluronate and hyaluronan, and, in fact, hyaluronic acid, is a polyanionic polymeric carbohydrate, due to the presence of

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deprotonated carboxylic acid moieties. Sodium salts are recognized as being pharmaceutically acceptable, thus, the inclusion of sodium cations to balance the charge of the negatively charged carboxylate groups of hyaluronic acid (i.e. sodium hyaluronate) is an obvious pharmaceutically acceptable variant of hyaluronic acid. Similarly, an ordinary skilled artisan would readily recognize that chondroitin is a polymeric carbohydrate containing carboxylic acid functional groups in its repeat units and that carboxylic acid groups can readily be deprotonated. Regarding the amounts of propylene glycol, active agent, and mucoadhesive polymer these were previously addressed in the office action mailed on October 6, 2007. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

The rejection of claim 25 under 35 U.S.C. 103(a) as being unpatentable over Greve et al. (U.S. Patent No. 5,801,199) in view of Jacob et al. (US 2003/0060486) as applied to claim 18-24 and 26-31 above, and further in view of Shahinian, Jr. (US 2004/0018252) (“Shahinian”) is maintained for the reasons of record set forth on pages 7-9 of the office action mailed on October 6, 2006.

#### ***Response to Arguments***

Applicants’ arguments filed April 6, 2007 have been fully considered but they are not persuasive. Applicants have traversed the instant rejection with the same arguments that have been addressed above. The rebuttal to these arguments is incorporated herein by reference.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

***Conclusion***

**Claims 18-47 are rejected. No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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